

Anticholinergic Agents for Overactive Bladder – Overview of Drug Information Service (DIS) Presentation

The primary document used for this review was prepared by the Oregon Evidence Based Practice Center. The overactive bladder (OAB) agents review was completed in December 2005 and includes efficacy and safety data for the OAB agents darifenacin, flavoxate, hyoscyamine, oxybutynin, scopolamine, solifenacin, tolterodine, and trospium. For these agents, the review assessed all available dosage forms, including immediate-release, extended-release, and transdermal products. The review focuses specifically on the comparative efficacy and safety of these agents in adults with urinary urge incontinence or overactive bladder.

Several companies submitted supplemental information for our review, including:

- GlaxoSmithKline / Astellas, the manufacturers of solifenacin (Vesicare),
- Allergan / Indevus, the manufacturers of trospium (Sanctura, Sanctura XR), and
- Novartis / Procter & Gamble, the manufacturers of darifenacin (Enablex).

The DIS reviewed the document and the supplemental information submitted to us. We came to the following conclusions:

- The efficacy and safety data for the included anticholinergic agents is current and complete.
- The document includes efficacy and safety information for scopolamine, an agent that is not labeled for this indication in the US.
- The document does not include efficacy and safety information for fesoterodine, a new anticholinergic agent for OAB that was approved in 2008.

The P&T Committee requested supplemental information on the following topics relative to the anticholinergic agents for OAB:

- List of agents used for OAB symptoms in the US and included in the Oregon review, along with information about dosage forms available and generic availability.
- Information about the efficacy and safety of fesoterodine, a new anticholinergic agent for the treatment of OAB.

The DIS will prepare an overview of this information and present it at the December P&T meeting.

December 4, 2008.